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Endoscopic extraperitoneal radical prostatectomy: critical analysis of outcomes and learning curve

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Study Type – Therapy (case series)
Level of Evidence 4

OBJECTIVE

To assess the outcomes and learning curve of extraperitoneal endoscopic radical prostatectomy (EERP) using cumulative summation charts from a single tertiary referral centre.

PATIENTS AND METHODS

The data from 300 consecutive men with localized prostate cancer who underwent EERP at Western General Hospital, Edinburgh, UK, between February 2006 and July 2009 were prospectively maintained in a database. The data collected included demographic details, perioperative outcomes, complications and follow-up for functional and oncology outcomes. The learning curve was analysed using generalized linear models for complication rate, operative time and blood loss, using procedure experience.

RESULTS

The mean (SD, range) operative duration was 160.52 (40.84, 100–310) min, and the intraoperative blood loss was 229.3 (172, 20–1000) mL. There was no conversion to open surgery and no patient required intraoperative blood transfusion. Only one of 250 (0.3%) patients required a blood transfusion after EERP. The median (range) hospital stay was 3 (2–20) days and the median catheterization time before cystography was 9 days. There was evidence that the complication rate reduced as experience was gained (odds ratio 0.98, 95% confidence interval, CI, 0.97–0.99; $P = 0.002$), with the estimated probability of a complication decreasing from 29% for the first to <1% for the 250th procedure. Also there was evidence of a decrease in operative duration (–0.0020 rate parameter on log scale; 95% CI –0.0024 to –0.0017; $P < 0.001$) and blood loss (–0.01 rate parameter on log scale; 95% CI –0.003 to –0.0002; $P = 0.021$). The positive surgical margin rate in pT2 disease decreased from 27% in the first 50 to 14.7% in the last 50 operated cases. The continence rate and biochemical recurrence-free rate at a minimum follow-up of 1 year for the first 100 patients was 89% and 94%, respectively.

CONCLUSION

The results from this series suggest that the benefits of minimally invasive surgery for localized prostate cancer (EERP) can be replicated after mentored fellowship training of a surgeon. The complication rate reduced substantially as experience was gained, suggesting a continuous surgical learning curve

KEYWORDS

prostate, carcinoma, laparoscopy, radical prostatectomy, learning curve, extraperitoneal

INTRODUCTION

Laparoscopic radical prostatectomy (LRP) is a well-established surgical procedure for localized carcinoma of prostate, with various reported advantages [1,2]. Since its introduction, the LRP has undergone significant surgical modifications, with improved functional and oncological outcomes [3,4]. The technically challenging nature of LRP remains one of the main reasons why it is difficult to learn [3,4]. This also acts as a barrier to the diffusion of the technique, in particular to small-volume centres. To facilitate more rapid learning and ensure patient safety, the procedure has been standardized and divided into various steps according to increasing level of complexity and difficulty (modular training) [5,6]. Furthermore, national guidelines such as those produced by the BAUS recommend identification of mentorship and prospective audit of outcome data for complex laparoscopic procedures such as extraperitoneal LRP to encourage the uptake of innovative techniques whilst maintaining good surgical practice [5].

Endoscopic extraperitoneal LRP (EERP) was introduced in Edinburgh, Scotland, in February 2006. In line with guidelines, we report the results of the newly established EERP services, with the following objectives:

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To critically appraise the perioperative, functional and oncological outcomes of the procedure in patients with localized prostate cancer; and to assess the learning curve using cumulative sum (CUSUM) analysis, and compare the results with those reported previously.

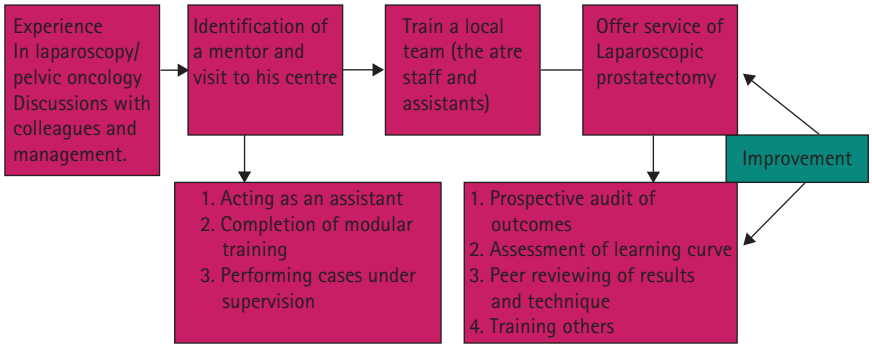
PATIENTS AND METHODS

One surgeon with interest and experience in laparoscopic urological surgery (A.M.C.) underwent modular training [7] for 3 weeks at the University of Leipzig, Germany. Modular training included stepwise progression and performance of surgical steps of EERP, intensive daily intracorporeal suturing on a pelvi-trainer, study of multimedia material, and acting as first assistant in EERP performed by experts on a daily basis. After successful modular training, the surgeon was mentored by in his first procedures in the UK, and kept in regular contact with the mentor thereafter. The design of laparoscopic services developed at our institution is shown in Fig. 1.

The technique of EERP was described previously [8]. Consecutive patients with localized prostate cancer opting for surgical treatment were offered LRP after careful counselling from February 2006 onwards at our institution. All of the first 100 patients were advised that nerve-sparing was unlikely to be possible, in view of the experience of the surgeon, as this is the most difficult aspect of the procedure in which to achieve competence. Pelvic lymphadenectomy was performed in patients with a PSA level of >10 ng/mL and a Gleason score of ≥7. The RP specimens were analysed by a specialist uropathologist using the Stanford technique [9].

Data from consecutive patients undergoing EERP between February 2006 and March 2009 at the Western General Hospital, Edinburgh, were prospectively entered into an electronic database. The database maintains comprehensive details, which include patient demographic characteristics, preoperative evaluation, intraoperative details, postoperative course, pathological analysis, complications before and after surgery, need for secondary interventions and length of hospital stay. The study population was divided into six groups according to the chronological order of their date of surgery.

FIG. 1. The development model of the Edinburgh LRP service.



The outcomes studied were: conversion of laparoscopic to open surgery, readmission to hospital within 30 days after discharge, secondary intervention, complications before and after EERP classified according to Clavien, and operative duration, calculated from the first skin incision to the application of dressings in theatre. The functional and oncological outcomes were estimated by incontinence rate, erectile dysfunction rate and rate of positive surgical margins (PSMs). The follow-up included 3-monthly clinic visits in the first year and 6-monthly in the second year and thereafter. At each visit the PSA level was recorded, with an assessment of functional outcomes, in a prospective database. Continence was defined as complete dryness (0–1 pad/24 h; pad for protection) and incontinence was quantified by the number of pads used in 24 h. Men wearing an occasional pad often do so for reassurance, rather than for significant urinary incontinence, and they were considered as continent [10]. Potency was assessed by asking the patient to assess whether there was any erection, quantified it as a percentage of a normal erection, and whether or not it was satisfactory for intercourse.

The continuous and dichotomous outcomes were used as proxies for the learning process. Outcomes were grouped by experience into six discrete chronological groups. A logistic regression model was used to evaluate the effect of experience (number of previous procedures) on the complication rate. Similarly, the effect of experience on operative duration and blood loss was assessed using linear regression with the natural log of the respective outcome modelled. A CUSUM plot of the complication rate was also generated. The split analysis using chronological groups was based on the previous work reporting a minimum of 46 cases required to overcome the learning curve using the technique of EERP offered to patients in this study [7]. The chi-squared and Mann-Whitney tests were used to assess the statistical trend of the differences between the groups and $2P < 0.05$ was considered to indicate significance.

RESULTS

Between February 2006 and July 2009, 300 consecutive patients with localized carcinoma of prostate underwent EERP at our institution, 123 (41%) with pelvic lymphadenectomy based on the criteria described above. The patient characteristics and baseline data are shown in Table 1. The mean (range) follow-up was 14.5 (1–38) months; 150 patients had a follow-up of ≥1 year. The perioperative details are shown in Table 2 for chronological groups of patients. There was no conversion to open surgery and no patient required intraoperative blood transfusion. Only one of 300 (0.3%) patients required a blood transfusion after EERP, at 7 days, having recommenced his anticoagulation therapy and having bled when the drain was removed. The mean hospital stay was 3 (2–20) days and the median catheterization time was 9 (8–19) days.

There were 19/300 (6.3%) complications after EERP, as assessed using Clavien classification [10]. Two patients had intraoperative complications (0.6%), both anterior rectal wall injuries, which were recognized during surgery and repaired endoscopically with two-layer suturing. One of these patients developed a recto-urethral fistula, which healed with no surgical intervention. Whilst no patients required immediate emergency

re-intervention, five required early re-intervention for complications (1.6%). These included two patients with a symptomatic lymphocele requiring percutaneous drainage; one anticoagulated patient with a large pelvic haematoma requiring open surgical drainage, and one patient with clot retention requiring cystoscopy, evacuation of clot and diathermy to bladder-neck bleeding vessels. One patient developed sepsis related acute tubular necrosis and was managed conservatively. Another patient required cystoscopy and stent removal under general anaesthesia for an inadvertent stent entrapment in the anastomotic suture during the anastomosis. There were no Clavien grade IV or V complications. A detailed description of all other complications and their management is shown in Table 3.

The pathological stage was pT2a in 41 patients (13.6%), pT2b in 12 (4%), pT2c/pT2+ in 171 (57%), pT3a in 56 (18.6%) and pT3b in 20 (6.6%). The PSM rates were analysed by dividing the patients into six groups of 50 in chronological order (Table 2). Five different locations of PSMs were identified; apex/urethra, basal, radial, multiple and subcapsular incisions. Most PSMs (42/84, 50%) were apical. Other PSMs on histological examination were basal, radial and multiple areas in seven (2.3%), 10 (3.3%) and eight (2.6%), respectively. A subcapsular incision was noted in 17 (5.6%) of the RP specimens. Of 45 patients with PSMs in pT2 disease, 41 (91%) had pT2c disease, reflecting a high volume of cancer in the RP specimen. There were two patients (5%) each in pTa and pT2b groups with PSMs.

There were 43 patients with PSMs in the first 150 cases with a follow-up of ≥1 year. Only six of them (4%) failed to have a PSA nadir of <0.1 ng/mL at their first follow-up. Four of these patients had pT3a disease with extensive cancer in the RP specimen but had organ-confined disease on preoperative staging; these patients received adjuvant external beam radiotherapy. Two patients with pT2 disease and PSMs had a PSA relapse at various times in their follow-up. Both of these patients had high-grade (Gleason grade 3 + 4 and 4 + 3, respectively) and high-stage disease (pT2c). Overall, the biochemical recurrence-free survival rate was 94.7% at 1 year.

TABLE 1 Demographic details of the 300 patients

Variable	Mean (SD, range), N or N (%)
Age, years	62.06 (46–76.5)
Preop PSA level, ng/mL	6.9 (3.73, 1.9–26)
Clinical stage	
T1b	2
T1c	109
T2a	116
T2b/c	73
Prostate volume, mL	47.86 (21.4, 18–251)
Previous TURP	2 (0.8)
Gleason biopsy score	
6	170 (56.6)
7	116 (38.6)
8	10 (3.3)
9	4 (1.3)
Pelvic lymph node dissection	123 (41)

TABLE 2 Operative and perioperative outcomes of EERP in different chronological groups of patients

Mean (SD), median (range), % or n/N (%) variable	Group 1	2	3	4	5	6	P
Order	0–50	51–100	101–150	151–200	201–250	251–300	
Peri-operative outcomes							
Operative duration, min	190 (46.92)	160 (35.7)	165 (34.49)	147 (31.9)	132 (33.39)	132 (26.8)	0.67
Blood loss, mL	200 (235.3)	100 (17.70)	250 (156.4)	200 (131.5)	177 (117.9)	205 (150.4)	>0.5
Transfusion rate	0	0	0	0	0	0	
Hospital stay, days	3 (1.4)	3 (1.4)	3 (2.3)	3 (0.8)	2.7 (1.3)	2.6 (1.3)	0.689
Duration of catheterization, days	9 (8–15)	9 (8–17)	9 (8–17)	9 (8–10)	9 (8–15)	9 (9–18)	>0.5
Complication rate	6	6	6	8	10	0	>0.5
Conversion rate	0	0	0	0	0	0	
Re-intervention rate	0	2	2	4	2	0	>0.5
Pelvic lymph node dissection						26 (52)	
PSM rate							
Overall	18 (36)	18 (36)	7 (14)	14 (28)	13 (26)	14 (28)	
T2 stage	11/40 (27)	8/34 (23)	5/38 (13)	11/38 (29)	5/29 (17)	5/34 (15)	
apical/subcapsular	9/11	7/8	4/5	8/11	3/5	3/5	
basal/radial	2/11	1/8	1/5	3/11	2/5	2/5	
T3 stage	7/10	10/16	2/12	3/12	8/21 (39)	9/16	
apical/subcapsular	5/7	6/10	0/2	1/3	3/8	4/9	
basal/radial	2/7	4/10	2/2	2/3	5/8	5/9	

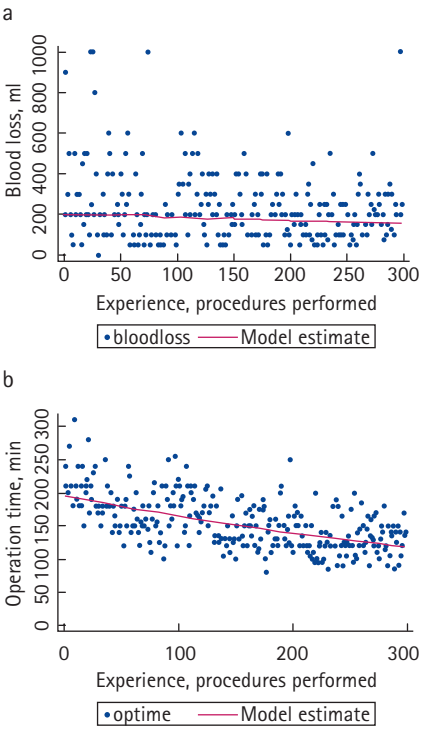
TABLE 3 Complications and their management

Clavien grade	Complication	n (%)	Management
I	Rectal injury	2 (0.6)	Two-layer suture
I	Urinary retention	2 (0.6)	Catheter 7–14 days
I	Lower limb ischaemia	1 (0.3)	Analgesia, antiplatelet and close clinical monitoring
I	Port-site abscess	1 (0.3)	Antibiotics and anti-inflammatory
II	Pulmonary embolism	1 (0.3)	Anticoagulation
II	UTI	2 (0.6)	Antibiotics
II	Respiratory infection	4 (1.2)	Antibiotics, chest physiotherapy
II	Port-site haematoma	1 (0.3)	Analgesics
IIIa	Symptomatic lymphocele	2 (0.8)	Percutaneous drainage
IIIa	Haematuria/clot retention	1 (0.3)	Cystoscopy/diathermy
IIIa	Stent entrapment in anastomotic suture	1 (0.3)	Cystoscopy and retrieval under general anaesthesia
IIIb	Pelvic haematoma	1 (0.3)	Open evacuation
IIIb	Sepsis and acute tubular necrosis	1 (0.3)	Managed conservatively

TABLE 4 Functional outcomes at 1 year for the first 150 patients

Functional Condition	n (%)
Urinary incontinence	
Completely dry or occasional pad for protection	132 (88)
Completely dry or occasional pad for protection	132 (88)
1–2- pads in 24 h	9 (6)
2–3 pads in 24 h	7 (4.6)
Sphincter placement	2 (1.3)
Potency rate	
Non-nerve sparing	101
Nerve sparing (extra-fascial)	15/33 (45)
Nerve-sparing (intra-fascial)	10/16
Biochemical failure	
PSA nadir of >0.1 ng/mL	6 (4)
PSA nadir of <0.1 ng/mL	2 (1.3)

*FIG. 2. Scatter plots of **a,** blood loss and **b,** operative duration, against the operating sequence.*



In all, 132 patients (88%) were continent in the first 150 patients in the series, while 6% wore one or two pads/day and 4.6% wore three or more. The mean time to continence was 6 (0–12) months. The potency rate was assessed in 49 patients in whom a nerve-sparing procedure (intra- or extrafascial) was recorded as having been attempted; 25 (44%) had good erections either spontaneously or with the help of phosphodiesterase inhibitors (Table 4).

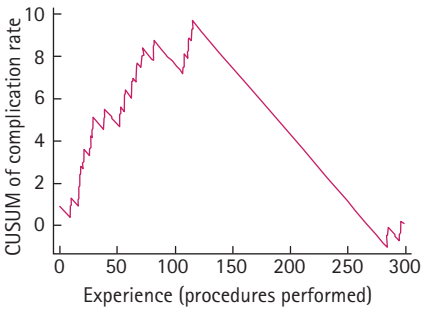
A scatter diagram of operative duration against the sequence number of the procedure is shown in Fig. 2b, and suggested a modest decrease in duration over time; most EERPs remained at ≈2 h. Similarly, Fig. 2a shows a variable amount of blood loss during EERP, but none of the patients received a blood transfusion during surgery. There was evidence that the complication rate reduced as experience was gained (odds ratio 0.98, 95% CI 0.97–0.99; $P = 0.002$) with the estimated probability of a complication decreasing from 29% for the first to <1% for the 250th procedure. The corresponding CUSUM plot for complication rate is shown in Fig. 3, which shows the classic 'n' shape expected for a downward trend. Also, there was evidence of a downward trend for operative duration (–0.0020 rate parameter on log scale; 95% CI –0.0024 to –0.0017; $P < 0.001$) and blood loss (–0.01 rate parameter on log scale; 95% CI –0.003, to –0.0002; $P = 0.021$). The clinical events for dichotomous variables such as complications, re-admissions, conversion to open surgery and secondary interventions, were too low and remained evenly distributed throughout the series precluding any statistical analysis of the learning curve.

DISCUSSION

EERP is gaining widespread acceptance as a first-line surgical therapy for localized prostate cancer in specialist European and worldwide centres. The principal findings of our study suggest that skills can be transferred through a mentored fellowship training programme and standardization of

technical steps of the EERP procedure. The report follows the present guidelines of national organization on training [5,11]. We could not determine any fixed number of procedures required to complete learning, but instead there was a continuous improvement in the outcomes. An audit of a newly established programme of LRP (EERP) in this study showed that the results are comparable to any of the initial reports of LRP (Table 5) [8,12–17]. The model of service development described in the present study, based on various stages of modular training and mentorship combined with rigorous scrutiny of results, could serve as guide to would-be RP centres in future, in particular minimizing the serious short- and long-term procedure-related complications [6].

FIG. 3. A CUSUM plot of the complication rate.



The learning curve of laparoscopic surgical interventions, in particular LRP, is steep. Although learning is based on a complex hierarchy of factors [18], the outcomes of the present study clearly suggest that proper training and mentorship can facilitate this process and help in reproducing the results. The standardization of technique and its division into different steps of increasing complexity for the purposes of learning remain germane to the dissemination of LRP [7,19]. The technique of EERP offered to patients in the present study has been standardized and well described in previous studies as a modular training model [20].

The learning curve in surgical interventions is usually estimated by measuring outcomes of procedures on a temporal basis. The present study provided a multidimensional evaluation of the learning curve using continuous and dichotomous variables as outcomes of surgical performance. These included operative duration, blood loss, hospital stay, conversion to open surgery, all serving as surrogate markers of the process of care. The clinical effectiveness of the procedure was estimated using various outcomes, e.g. complication rate, rate of re-interventions, and functional and oncological outcomes. Previous reports have suggested that the learning curve in LRP is 40–50 cases [21]. However, our results suggest that there is a continuous learning; this observation underscores the importance of a high level of experience required for optimal outcomes in LRP, similar to outcomes in a recent multi-institutional retrospective study [21]. CUSUM analysis (a sensitive method to quickly represent a change in performance) described the outcomes of consecutive procedures in the study. This statistical method provided an objective assessment of the quality assurance of LRP.

Various studies have also shown that the number of intraoperative complications, conversion rate and morbidity decreased with increasing experience [14,15]; however, this might mirror the standardization and development phase of the technique. We had no conversions to open surgery and the complication rate was less than reported in the previous studies.

TABLE 5 Previous reports of the perioperative, oncological and functional outcomes of LRP during the learning curve

Variable	Study [13]	[16]	[12]	[8]	[15]	[17]	[14]	Present
N patients	100	200	50	70	180	125	120	300
Perioperative								
Blood loss, mL								
median	313	–	680	–	–	185	402	200
range	300–1300		–	–	–	–	50–1500	0–1000
Transfusion rate, %	3	5	13	7	31	1.5	10	0.3
Mean (range) hospital stay, days	4.2 (3–13)	– (2–5)	–	–	–	–	–	3 (2–20)
Complication rate, %	11	12	–	10	18.8	4	–	9
Catheterization, days	Variable	–	–	–	5.5	–	6.2 (2.2)	9 (8–17)
Conversion rate, %	1	–	2	0	–	0	5.8	0
Oncological/functional								
PSM rate, %	16	27	22	6.1 (pT2) 35.1 (pT3,4)?	2.3 (pT2) 15–34 (pT3a-b)	–	15	28
Rates, %								
Biochemical failure (mean follow-up, months)	0 (9.8)	5	4	–	5	–	5	5.3
Urinary continence (follow-up, months)	90 (12)	88 (6)	85 (6)	–	97 (22)	86 (6)	72 (6)	88 (12)
Potency	62	46	67	–	4/10	–	45	51 (25/49 at 1 year)

The crucial step in establishing any new surgical technique in prostate cancer is to maintain or improve the quality of surgical care, which should be reflected in low complication rates, and good oncological and functional results. In evaluating the 'quality' of a 'standard retropubic RP' (either open or laparoscopic), Van Hoppel *et al.* [22] proposed that the analysis of 10 consecutive RPs for T1/T2 prostate cancer should give a mean blood transfusion need of <3 units, a mean operative duration of <3 h, a mean occurrence of PSMs in <20%, a PSA level below the detection limit at 3 months in >80% and complete urinary continence at 3 months in >50% of patients. The outcomes in the present study achieve these minimum standards and reflect the significant advantages of EERP over the open technique in many areas described in that report.

The rate of complications in the present series, as assessed using robust and comprehensive Clavien classification, was low (18/200, 9%). The incidence of intraoperative complications was 0.6% (Grade I). Early re-intervention was necessary in three of 250 (1%) (Grade IIIa, IIIb) and late re-intervention in one of 300 (0.3%) complications, with 17/18 (95%) of these complications occurring in the first half of our series. The Montsouris group reported an overall complication rate of 17.1% with a major complication rate of 5.3% in their initial 3 years of experience of LRP [23]. Eden *et al.* [13], in their first 100 cases of LRP in a UK centre, reported a major complication rate of 3%, all of which required early intervention during ot after RP (one rectal injury, one urinary peritonitis and one haemorrhage from the neurovascular bundle). Their late operative re-intervention rate was 6% (two bladder neck stenosis; four port-site hernia). In the present series there were no bladder neck complications or stenoses, which largely reflects the technique of EERP. The Leipzig group published a series of 900 patients having EERP, with complications classified according to the modified Clavien system (similar to that used in the present study). Their incidence of intraoperative complications was 0.6% (Grade I, IIIa). Early operative intervention was required in 3% cases (Grade IIIa, IIIb) and late re-intervention in 0.5% patients (Grade IIIa, IIIb) [24].

The overall PSM rate in the present study is comparable to that in contemporary series (Table 5). Most of the PSMs were in the apical area and decreased after the first 200 cases in the series, possibly suggesting an improvement in the apical area dissection. The biochemical recurrence-free survival rate was 94.7% at a mean follow-up of 12.5 months for the first 150 patients. PSMs after RP have been reported in 5–43% of RP specimens [25]. Many factors, including cancer volume, its location, surgical technique and pathological technique of specimen processing, contribute to the rate of PSMs. Whether margin status is a manifestation of disease aggressiveness or a consequence of surgical technique remains unclear. Whilst the data of the present study have not matured enough to correlate margin status with biochemical and clinical progression, the early follow-up at 12 months showed a large discrepancy between the PSM rate (43/150, 28.6%) and biochemical failure rate (eight of 150, 5.3%). Most of these latter patients (six) failed to achieve a nadir PSA of <0.1 ng/mL, suggesting the possibility of systemic disease in addition to a PSM. The incongruity between PSM rates and biochemical recurrence might be explained by most PSMs being an apical or capsular incision, which are associated with a low rate of biochemical failure [23,26]. Our results are shown alongside those of other series reporting their first series of LRP (Table 5), acknowledging that results from many of these previous series were published during the developmental phase of LRP; nonetheless, these represent outcomes from high-volume laparoscopic surgery centres and form a useful benchmark.

Furthermore, variations in the PSM rates in case series reporting their first experience of LRP can be partly explained by the techniques of pathological analyses of the RP specimen and the policy of routinely obtaining intraoperative frozen sections.

The overall continence rate at the 1-year follow-up in our series was 88% (Table 4). This continues to improve with increased surgical experience and modification of technique in the form of intrafascial dissection of prostate.

In conclusion, the outcomes of the present study suggest that the optimal technical skills of LRP necessary for the safety of patient can be gained through proper training and mentorship. The latter helping to shorten the learning curve and achieve the reproducibility of results.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **(L)(EE)**, (laparoscopic) (endoscopic extraperitoneal) radical prostatectomy; **PSM**, positive surgical margin.